Clinical Investigation

Coronary Artery Bypass Surgery versus Coronary Stenting

Risk-Adjusted Survival Rates in 5,619 Patients

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We used the Texas Heart Institute Cardiovascular Research Database to retrospectively identify patients who had undergone their 1st revascularization procedure with coronary artery bypass surgery (CABG; n=2,826) or coronary stenting (n=2,793) between January 1995 and December 1999. Patients were classified into 8 anatomic groups according to the number of diseased vessels and presence or absence of proximal left anterior descending coronary artery disease. Mortality rates were adjusted with proportional hazards methods to correct for baseline differences in severity of disease and comorbidity.

We found that in-hospital mortality was significantly greater in patients undergoing CABG than in those undergoing stenting (3.6% vs 0.75%; adjusted OR 8.4; P *<0.0001). At a mean 2.5-year follow-up, risk-adjusted survival was equivalent (CABG 91%, stenting 95%; adjusted OR 1.26;* P *= 0.06). When subgroups matched for severity of disease were compared, no differences in risk-adjusted survival were seen. A survival advantage of stenting was noted in 3 categories of patients: those >65 years of age (OR 1.33,* P *= 0.049), those with non-insulin-requiring diabetes (OR 2.06,* P *= 0.002), and those with any noncoronary vascular disease (OR 1.59,* P *= 0.009).*

In this nonrandomized observational study, CABG had a higher periprocedural mortality rate than did percutaneous stenting. At 2.5 years, however, the survival advantage of stenting was no longer evident. These data suggest that there is no intermediate-term survival advantage of CABG over stenting in patients who have multivessel disease with lesions that can be treated percutaneously. ***(Tex Heart Inst J 2002;29:3-9)***

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Percutaneous transluminal coronary angioplasty (PTCA) reduces symptoms of angina, but its application has been limited in patients with multivessel coronary artery disease (CAD) because of a significant risk of periprocedural ischemic complications and moderate long-term efficacy.[1-4] Nevertheless, in well-defined subsets of patients with multivessel CAD, PTCA (although hampered by a more frequent need for subsequent procedures), may offer a survival probability similar to that of coronary artery bypass surgery (CABG).[5-11] Coronary stent implantation improves on balloon angioplasty alone, both by reducing the risk of emergent referral for CABG and by improving long-term efficacy.[12,13] Percutaneous revascularization using coronary stents (PCI-stenting) is rapidly becoming the most frequently used method to treat coronary artery occlusive disease of almost any severity. However, stent implantation has not prevented restenosis: an event that may be clinically unrecognized in as many as half of cases. Therefore, PCI-stenting could be associated with a reduced probability of survival over time, due to the increased risks associated with subsequent disease progression and with the performance of additional revascularization procedures.

In order to ascertain the impact of the initial revascularization method on survival rates, we examined the survival outcome of 5,619 patients who had undergone their 1st revascularization procedures at our institution, either with CABG or with PCI-stenting. Preoperative clinical and anatomic variables were examined to detect predictors of outcome, and risk-adjusted survival rates of CABG and PCI-stenting were compared in patients classified according to the number of diseased vessels and the location and severity of disease.

Patients and Methods

Patient Population. The Texas Heart Institute (THI) Cardiovascular Research Database was used to identify patients who had undergone CABG or PCI-stenting as their 1st revascularization procedure between 1 January 1995 and 31 December 1999. Patients were excluded if they had left main coronary artery disease (stenosis ≥50%), had experienced an acute myocardial infarction during the 24 hours before revascularization, or had undergone concomitant surgery with the CABG. The study was limited to residents of Texas.

Each patient was classified into 1 of 8 anatomic groups according to the number of vessels diseased and the presence or absence of ≥50% stenosis in the proximal region of the left anterior descending coronary artery (LAD). Subset analyses were then performed using the following variables: age; sex; ejection fraction; number of vessels diseased; and the presence or absence of diabetes mellitus, renal insufficiency, or any noncoronary vascular disease.

Definitions. The following definitions were used for the purpose of this study:

- *Single-vessel disease:* The presence of a ≥50%-diameter lumen narrowing in the LAD, the left circumflex or right coronary artery, or a major branch of any of these.
- *Double-vessel disease:* The presence of a ≥50%-diameter lumen narrowing in 2 of the 3 major epicardial vessel systems.
- *Triple-vessel disease:* The presence of a ≥50%-diameter lumen narrowing in all 3 major epicardial vessel systems or in the LAD and proximal circumflex artery in left-dominant systems.
- *Left main disease:* The presence of a ≥50%-diameter lumen narrowing in the left main coronary artery.
- *Proximal LAD disease:* The presence of a ≥50%-diameter lumen narrowing occurring anywhere from the ostium of the LAD to the takeoff of the 1st diagonal artery or to the 1st septal artery if the septal artery takeoff is distal to that of the diagonal artery.
- *Angina:* The Canadian Cardiovascular Society criteria.
- *Congestive heart failure:* The New York Heart Association criteria.
- *Postoperative myocardial infarction:* The elevation of creatine phosphokinase (CPK) and CPK-MB ≥3 times the upper limits of normal or the presence of new Q waves on follow-up electrocardiograms.

Variables defined by patient history included hypertension, severity of angina, congestive heart failure, family history of CAD, previous myocardial infarction, renal insufficiency, diabetes mellitus, peripheral vascular disease, transient ischemic attack, cerebrovascular disease, abdominal aortic aneurysm, and chronic obstructive pulmonary disease. Patient histories were obtained by interviews at the hospital or at clinic presentation and were then entered prospectively into the database.

Coronary Stenting and CABG Procedures. All percutaneous procedures included coronary stents and were performed with techniques in standard use at the time of the procedure. These methods have been described.[14] Standard surgical techniques, extracorporeal circulation, and myocardial protection were used in patients undergoing CABG.[15]

Patient Follow-Up and Endpoints. Follow-up information was obtained from the THI Cardiovascular Research Database and the Texas vital statistics system to determine whether any of the patients had died during our designated study period and, if so, at what interval after the procedure. The endpoint was all-cause mortality.

Statistical Analysis. Baseline characteristics are presented as mean values with standard deviation or as a percentage of total patients with available data from each group. Pearson's χ^2 test for discrete variables and the Student's *t*-test for continuous variables were used for comparisons. Clinical and angiographic characteristics were then defined for each group. The SAS VAX/VMS Version 6.09 (SAS Institute; Cary, NC) was used for analysis. A P value of <0.05 was considered significant.

Logistic regression and Cox proportional hazards models were developed with a forward stepwise variable selection process to determine which clinical and angiographic variables were associated with early mortality. The type of procedure (CABG or PCI-stenting, coded as 1 and 0, respectively) was then added to the models to determine whether survival was dependent on the type of intervention, while controlling for significant patient risk factors. The exponential of the coefficient of this variable was the CABG:stenting odds ratio or hazard ratio.

The 2.5-year survival of the 2 treatment groups was compared for each of the anatomic subgroups and the prespecified subsets. A different model was used for each group with the use of Cox proportional hazards models, which retain only the significant predictors of survival. Confidence intervals of 95% for the hazard ratios were calculated to test for significant differences in survival between the groups undergoing CABG and PCI-stenting.

In order to measure survival differences in terms of percentages rather than in relative terms for each anatomic subgroup and the various subsets, a Cox proportional hazards model for each subgroup was used to construct adjusted Kaplan-Meier survival curves for the 2 treatment groups. The adjusted survival rates were calculated from the Cox models, setting the coefficients for the other covariates at their means and varying the coefficient for the procedure. The resulting 2 curves were plotted for the anatomic subgroups and the clinical subsets for comparison.

Results

During the period reviewed, 5,619 patients underwent either CABG (n=2,826) or coronary stenting (n=2,793) as their 1st revascularization procedure at our institution. Compared with patients referred for PCI-stenting, those referred for CABG were older, had lower ejection fractions, and more often reported a history of symptomatic congestive heart failure, chronic obstructive pulmonary disease, cerebrovascular disease, and peripheral vascular disease. Patients referred for CABG were also more likely to have diabetes mellitus or multivessel disease.

The patients treated with stents comprised 29%, 59%, 73%, 86%, and 89% of 1st-time percutaneous interventions during each of the inclusive years, respectively, and 69% overall. Stent patients were more often female, hyperlipidemic, had a higher previous incidence of myocardial infarction, and had a family history of CAD (Table I).The mean follow-up period was 2.5 ± 1.4 years. Follow-up information was obtained for 100% of patients in both treatment groups.

The observed (unadjusted) in-hospital mortality rates for the CABG and PCI-stenting groups were 3.6% and 0.75%, respectively (adjusted odds ratio [OR] 8.43 [95% CI 4.2–16.9], P <0.0001). Table II presents the multivariate correlates of in-hospital mortality.

The overall survival rates of patients treated with either CABG or PCI-stenting are shown in Figure 1. At a mean follow-up interval of 2.5 ± 1.4 years, the unadjusted survival rates for CABG and stent patients were 91% and 95%, respectively (adjusted rates were 94% vs 95%, OR 1.26 [95% CI 0.99–1.59], P = 0.06). The multivariate predictors of intermediate-term (2.5-year) mortality are presented in Table III.

The observed and adjusted follow-up survival rates for each of the 8 anatomic subgroups are presented in Table IV. The adjusted odds ratios for CABG death:PCI-stenting death in each of the anatomic subgroups are presented in Figure 2. These ratios showed no significant treatment-related differences in survival across the anatomic subgroups.

Subset analyses are presented in Figure 3. A survival advantage was observed for the following PCI-stenting patients: those older than 65 years (adjusted OR 1.33, P = 0.049); those with non-insulin-requiring diabetes mellitus (adjusted OR 2.06, P = 0.002); and those with any noncoronary vascular disease (adjusted OR 1.59, P = 0.009). No treatment-related differences in survival were noted across the following subsets: sex, number of vessels diseased, ejection fraction, and the presence or absence of renal insufficiency.

TABLE I. Clinical and Angiographic Characteristics of CABG Group (N=2,826) and Stenting Group (N=2,793)

Characteristic	CABG (%)	Stent (%)	*P* Value
Age >65 years	45.4	37.0	<0.0001
Female	25.9	30.6	<0.0001
Hypertension	68.2	67.4	0.54
Smoking	54.6	54.7	0.93
Hypercholesterolemia	51.7	62	<0.0001
Unstable angina	61.9	63.4	0.35
NYHA class III–IV	84.2	54.4	<0.0001
Congestive heart failure	13.4	8.02	<0.0001
Ejection fraction <50%	37.9	27.2	<0.0001
Family history of CAD	41.4	46	0.0005
Prior myocardial infarction	16.5	23.3	<0.0001
Cerebrovascular disease	6.06	4.4	0.006
Prior TIA	3.2	2.4	0.08
Peripheral vascular disease	17.4	12.4	<0.0001
COPD	25.2	22.4	0.016
Diabetes: any type	33.9	22.9	<0.0001
Diabetes: insulin-requiring	11.9	5.4	<0.0001
Renal insufficiency	10.2	9.13	0.18
Number of vessels diseased			<0.0001
1	7.1	46.7	—
2	24.7	34.0	—
3	64.4	12.8	—
Obesity	19.4	21.4	0.07
Valvular disease	2.9	3.9	0.036
Neoplasm	12.6	10.9	0.053

CABG = coronary artery bypass surgery; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; TIA = transient ischemic attack

TABLE II. Multivariate Correlates of In-Hospital Mortality

Variable	OR	95% CI	*P* Value
CABG	8.4	4.2 –16.9	<0.0001
Low ejection fraction	1.8	1.2 – 2.7	0.0058
Age >65 years	2.5	1.6 – 3.9	<0.0001
Renal insufficiency	3.9	2.4 – 6.1	<0.0001
Prior TIA	2.5	1.2 – 5.3	0.016
Cerebrovascular disease	2.37	1.1 – 3.8	0.016
COPD	1.7	1.1 – 2.5	0.017
Pre-IABP	9.7	5.4 –17.6	<0.0001

CABG = coronary artery bypass surgery; COPD = chronic obstructive pulmonary disease; OR = odds ratio; Pre-IABP = preprocedural use of an intra-aortic balloon pump; TIA = transient ischemic attack

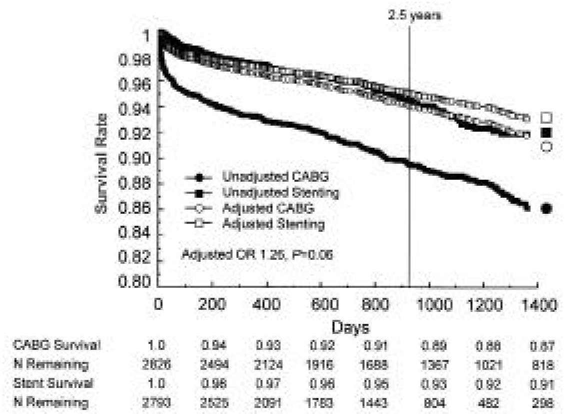

Fig. 1 *Adjusted and unadjusted survival rates in all patients treated with CABG or PCI-stenting.*

CABG = coronary artery bypass surgery; PCI = percutaneous intervention

TABLE III. Multivariate Correlates of Intermediate-Term (2.5-Year) Mortality

Variable	OR	95% CI	*P* Value
Number of vessels diseased	1.3	1.1 – 1.4	0.004
Pre-IABP	3.7	2.6 – 5.2	<0.0001
Age >65 years	2.1	1.7 – 2.6	<0.0001
Renal insufficiency	2.2	1.7 – 2.8	<0.0001
COPD	1.4	1.2 – 1.8	0.0004
Prior TIA	1.7	1.2 – 2.5	0.004
Cerebrovascular disease	1.9	1.5 – 2.5	<0.0001
Congestive heart failure	2.1	1.7 – 2.6	<0.0001
Peripheral vascular disease	1.5	1.2 – 1.9	<0.0001
Diabetes	1.5	1.2 – 2.0	0.0008

COPD = chronic obstructive pulmonary disease; OR = odds ratio; Pre-IABP = preprocedural use of an intra-aortic balloon pump; TIA = transient ischemic attack

Discussion

Coronary stents have substantially improved the safety and efficacy of percutaneous revascularization. The attendant risk of emergency referral for CABG and the need for subsequent revascularization procedures have been reduced by more than 50%.[12] Physicians have become increasingly adept in the application of percutaneous revascularization, often treating patients with levels of disease severity that would clearly indicate the use of CABG. As a result, the comparative value of CABG and PCI-stenting has been questioned. From the experience at a single institution, we studied the comparative survival rates of patients after a 1st revascularization procedure with either CABG or PCI-stenting.

Comparisons of PTCA and CABG have been made in 7 randomized trials designed to identify the most effective alternative for selected patients with multivessel CAD in whom both methods were deemed feasible.[5-11] The individual results of these trials and a meta-analysis of their combined results have consistently shown equivalent survival rates with use of the 2 strategies over approximately 5 years of follow-up, albeit at the price of an increased need for subsequent revascularization procedures in the PTCA-treated patients.[16] None of these trials differentiated proximal from nonproximal LAD involvement, and the use of stents was limited. The most important observation gleaned from these trials at their current stage of follow-up is that—in the small subset of patients who have multivessel disease treatable by either method—the probability of survival is not altered by delaying surgery in favor of PTCA.

Nonrandomized observational studies from 2 large databases have added to the results of randomized trials studying the impact of stenosis location on the relative superiority of angioplasty or CABG.[17,18] The

TABLE IV. Intermediate-Term (2.5-Year) Survival According to Treatment in Each of the 8 Anatomic Groups

	No. of Patients*		Observed Survival (%)		Adjusted Survival (CABG:Stent)		
Anatomic Group	CABG	Stent	CABG	Stent	OR	95% CI	*P* Value
Single-Vessel							
No LAD	18	480	95	95	0.33	0.04 – 2.5	0.28
Nonproximal LAD	44	367	93	96	2.4	0.73 – 4.0	0.14
Proximal LAD	91	363	95	91	0.64	0.24 – 1.7	0.37
Double-Vessel							
No LAD	40	116	91	95	1.6	0.66 – 4.0	0.29
Nonproximal LAD	256	645	93	95	1.4	0.73 – 2.7	0.31
Proximal LAD	290	256	92	93	1.06	0.49 – 2.3	0.87
Triple-Vessel							
Nonproximal LAD	1,058	405	89	92	1.4	0.82 – 2.2	0.24
Proximal LAD	992	118	85	80	0.93	0.53 – 1.6	0.79

CABG = coronary artery bypass surgery; LAD = left anterior descending coronary artery; OR = odds ratio

*Total does not match number of patients in study due to the exclusion of some records during statistical modeling.

Duke University database[17] was used to examine the outcomes of 9,263 patients whose treatment decisions were made by individual clinical practitioners. Patients were classified on the basis of the anatomic severity of disease, and statistical models were used to adjust for clinical characteristics that might affect long-term outcomes. The results indicated that PTCA was the most effective therapy for patients with single-vessel disease, unless they had subtotal occlusion of the proximal LAD. Patients with double-vessel disease or subtotal occlusion of the LAD had equal results with either method. Patients with triple-vessel disease and those who had double-vessel disease with proximal LAD stenosis survived longer with surgery.[17] The New York State cardiac surgery and angioplasty registries[18] were similarly classified and analyzed. Three-year survival rates were compared for patients undergoing CABG (n=29,646) and those undergoing PTCA (n=29,930); only 12% received stents. The results suggested that PTCA was the better treatment for patients who had single-vessel disease with no LAD involvement. Patients with nonproximal LAD disease or double-vessel disease had equally good results with either method. Patients with proximal LAD disease or triple-vessel disease fared better with surgery.[18]

In our study, the observed in-hospital mortality rates for CABG patients compared with PCI-stenting patients were consistent with results reported in the randomized trials.[5-11] In those trials, the in-hospital mortality for CABG ranged from 1.0% to 4.6%, and that of PTCA ranged from 1.0% to 1.8%. The New York study,[18] which included a lower proportion of patients with high-risk variables than did our study, reported in-hospital mortality rates for CABG and PTCA of 1.9% and 0.4%, respectively. These data are consistent with results from ongoing randomized trials comparing multivessel stenting with CABG.[19,20]

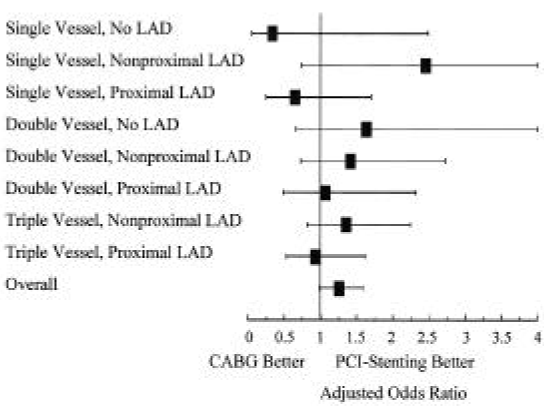

Fig. 2 *Adjusted odds ratios comparing the results of CABG and PCI-stenting in the 8 anatomic subgroups.*

CABG = coronary artery bypass surgery; LAD = left anterior descending coronary artery; PCI = percutaneous intervention

The ERACI II group (Argentine Randomized Study: Coronary Angioplasty with Stenting vs Coronary Bypass Surgery in Multivessel Disease)[19] reported in-hospital mortality rates of 5.7% and 0.9% for CABG and stenting, respectively. The ARTS trial (Arterial Revascularization Therapy Study)[20] reported a composite incidence of death, myocardial infarction, or stroke in 6% of the patients undergoing CABG and in 5% of those undergoing stenting.

After adjustment for baseline differences and the establishment of essential equivalence in anatomic severity of disease, our data showed equivalent survival rates at 2.5 years for the 2 strategies. These findings parallel the results of earlier randomized trials comparing PTCA with CABG.[5-11] This is in contrast with 3 current randomized trials, the results of which conflict with one another.[19-21] The follow-up results of the ARTS trial[20] showed no significant differences in 1-year mortality between the CABG and stenting groups (2.8% vs 2.5%, respectively). In the ERACI II trial,[19] a 1-year survival advantage was noted for stenting over CABG (96.9% vs 92.5%, respectively; P <0.017). Most recently, the SoS Trial (Stent or Surgery Trial)[21] reported higher all-cause mortality for stent-treated patients than for CABG patients at 1 year (2.5% vs 0.8%, respectively; P = 0.007), a finding that the investigators attributed to improved outcomes after CABG.[21]

Perhaps the most important observation from our study was the absence of survival differences in patients with triple-vessel disease, with or without proximal LAD involvement, after 2.5-years of follow-up; previous studies have shown CABG to be superior in these patients.[17,18] The absence of a survival difference

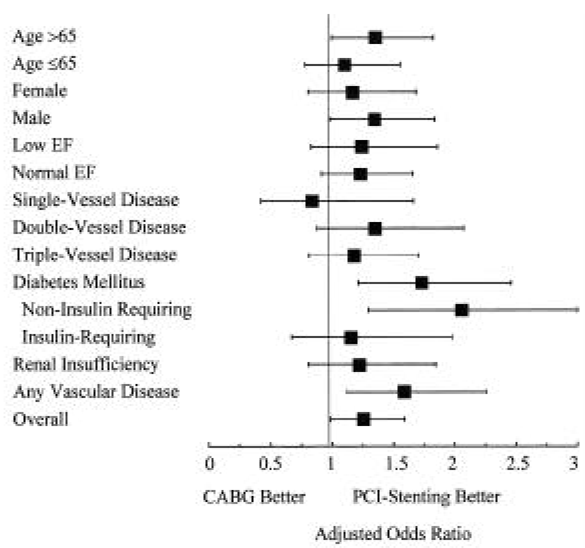

Fig. 3 *Adjusted odds ratios comparing the results of CABG and PCI-stenting in the various prespecified subsets.*

CABG = coronary artery bypass surgery; EF = ejection fraction; PCI = percutaneous intervention suggests that the improved efficacy of PCI-stenting makes this method available to a subset of patients who might previously have been expected to survive better after CABG. Many of the patients in this study were treated before the routine use of newer-generation stents, improved techniques, and potent antiplatelet therapies. These advances have undoubtedly improved the safety and the long-term efficacy of percutaneous revascularization.[13,22-24]

Subgroup Analysis. Subgroup analyses in our study revealed a survival advantage with initial stent revascularization in those patients who were more than 65 years of age, those who had non-insulin-requiring diabetes mellitus, and those who had any noncoronary vascular disease. Age above 65 years, noncardiac vascular disease, and diabetes mellitus identified patients who were at increased risk of complications after any procedural intervention. Examination of the point estimates of risk-adjusted survival revealed early separation of the surgical and PCI-stenting populations early after their revascularization procedures. Afterwards, event rates were comparable, causing the subsequent survival curves to be parallel. Therefore, the 2.5-year survival advantage of PCI-stenting may be due to the effect of early surgical hazard characterized by an unequal prevalence of procedural risk. Because these populations are associated with a heightened risk of subsequent disease progression, it is highly possible that longer follow-up will reveal the disappearance of this apparent survival advantage. This speculation is derived from large, randomized trials comparing early CABG with medical therapy,[25-27] wherein a separation of survival curves began 4 to 5 years after treatment. Continued observation is clearly necessary.

Study Limitations. One of the more obvious limitations of this study is that it was not randomized; moreover, the choice of revascularization method is generally influenced heavily by physician opinion. We attempted to reduce this bias by adjusting for differences among many clinical and angiographic variables. Nonetheless, it remains unclear whether multivariate analysis can overcome such a bias. Another limiting factor is that improvements in procedural technology and techniques during the interval required for follow-up might have partially invalidated our findings with regard to therapy performed before these improvements; this is particularly true in the case of coronary stenting.

The fact that this was a single-center experience naturally raises the question of whether these results are applicable to other populations. Another possible bias is the relatively short follow-up period (2.5 years), which gave a clear advantage to PCI-stenting in view of the early hazard of surgery. In addition, because of limited resources, we were able to track deaths in Texas residents only. To minimize this bias, we restricted our study population to patients who were residents of Texas when their procedures were performed. Consequently, we were unable to track deaths of patients who had moved out of state. Another limitation was the use of all-cause mortality as the endpoint. This was necessary because autopsy data were not available, and the cause of death listed in the record was not considered sufficiently accurate to identify cardiac death. Finally, we did not include freedom from symptoms or incidence of repeat revascularization in our research. Despite these limitations, we consider the follow-up data for our sole endpoint—death and its relationship to the 1st revascularization method chosen—to be irrefutable.

Studies derived from observational databases provide an important supplement to the information gleaned from randomized trials: the costs are lower, large numbers of patients are available, the data are derived from "real-world" patient records, the data are more current, and the studies can be more easily designed to take advantage of improved statistical power. Furthermore, from a historical point of view, findings from studies of observational databases have been consistent with the results of randomized trials.[28,29]

Conclusions

In this nonrandomized, retrospective, observational database study, patients for whom stent revascularization was chosen as the initial revascularization method had a lower early risk and equivalent intermediate-term outcome in comparison with those who underwent CABG, regardless of the anatomic severity of the disease. We conclude that, in patients with multivessel CAD and lesions treatable with PCI, an initial use of percutaneous revascularization with coronary stents rather than the use of CABG is not associated with a reduction in observed or risk-adjusted survival. Observations from the subgroup analyses warrant further investigation.

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